



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,219	10/19/2005	Kenneth Michlitsch	31698-01361	8323
71040 7590 11/21/2007 LUCE, FORWARD, HAMILTON & SCRIPPS 11988 EL CAMINO REAL, SUITE 200 SAN DIEGO, CA 92130			EXAMINER NEAL, TIMOTHY J	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 11/21/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

10/523,219

### Applicant(s)

MICHLITSCH, KENNETH

### Examiner

Timothy J. Neal

### Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) 27-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-26, 31-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

This action is in response to the amendments and Request for Continued Examination filed on 08/27/2007.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 21-26, 31-33, and 37-40** are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (US 5,545,178).

Kensey discloses:

**21.** A device for sealing a puncture tract by forming and extruding an autologous plug within the puncture tract, wherein the puncture tract is disposed within tissue proximal to a vessel, the device comprising: a housing comprising an outer tube (Figure 1 Item 64) and an inner tube, the inner tube having a lumen (Fig 1 Item 84) in flow communication with the puncture tract and the vessel, the inner tube further having a plurality of openings (Figure 1, distal and proximal openings of Item 84) in fluid communication with the outer tube, a volume of blood provided in the lumen being mixable with a blood coagulating agent provided to the volume of blood (Column 11 Lines 22-33); a closure

element (Fig 1 Item 38) configured to be inserted from the housing into the puncture tract and to isolate the volume of blood admixed with the blood congealing agent from the vessel during formation of the autologous plug from the volume of blood by action of the blood congealing agent; and a plunger (Fig 1 Item 76) disposed for translation within the lumen to extrude the autologous plug formed within the lumen.

**22.** The device of claim 21, wherein the housing comprises a second lumen defined by an annular interstice between the outer tube and the inner tube (Fig 1).

**23.** The device of claim 22, wherein the second lumen is disposed within the plunger (Fig 1 Item 84).

**24.** The device of claim 21, wherein the autologous plug formed in the lumen has a length and a form factor that causes the autologous plug to engage tissue surrounding the puncture tract after ejection by the plunger into the puncture tract (Fig 5).

**25.** The device of claim 21, wherein the closure element comprises a pledget and thread (Fig 1 Item 38 and Items 42A and 42B).

**26.** The device of claim 25, wherein at least one of the pledget and the thread is biodegradable (Col 8 Line 60 and Col 9 Line 35).

**31.** The device of claim 21, wherein the blood congealing agent is pre-disposed within the lumen (Fig 1 Item 36).

**32.** The device of claim 31, wherein the blood congealing agent is coated onto an interior surface of the lumen (Col 10 Line 2).

**33.** The device of claim 21, wherein the blood congealing agent is introduced into the lumen through the plurality of opening[s] (Column 10 Line 2).

**37.** The device of claim 21, wherein the blood congealing agent comprises a matrix (Col 8 Line 25).

**38.** The device of claim 37, wherein the matrix is chosen from the group consisting of gauze, biocompatible foam, and spun fiber (Col 8 Line 25).

**39.** The device of claim 37, wherein the matrix is biodegradable (Col 8 Line 25).

**40.** The device of claim 37, wherein the matrix comprises at least one channel disposed therethrough (Fig 1 Item 36).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 34 and 35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey (US 5,545,178) in view of Greenhalgh (U.S. 6,391,037).

Kensey discloses the invention substantially as claimed as stated above.

Kensey does not disclose the blood congealing agent comprises a platinum wire; the blood congealing agent comprises a thermo-resistive wire.

Greenhalgh teaches a platinum and thermo-resistive wire (Col 1 Line 52) to clot blood. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Kensey's wound sealing apparatus to include Greenhalgh's platinum and thermo-resistive wires. Such a modification would promote blood clotting.

**Claim 36** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey (US 5,545,178) in view of Hannam et al. (US 5,649,959).

Kensey discloses the invention substantially as claimed as stated above.

Kensey does not disclose the claimed blood congealing agent. Hannam teaches the use of fibrin and thrombin (Column 9 Line 22) to promote hemostasis. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the

invention was made to modify Kensey's congealing agent to include Hannam's fibrin and thrombin. Such a modification would promote hemostasis.

### ***Response to Arguments***

Applicant's arguments filed 08/27/2007 have been fully considered but they are not persuasive.

The Applicant has argued that Kensey does not anticipate the claimed invention because it does not disclose an inner and outer tube. The Examiner disagrees. The rejection set forth above indicates the inner and outer tubes. The Applicant has made no further arguments.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

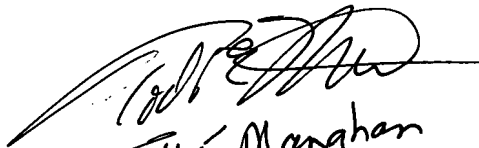
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:  
10/523,219  
Art Unit: 3731

Page 7

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN



Todd E. Manahan  
SPE 3731